Title: **510(k) SUMMARY**
Quanta System Cyber Tm 150W

K102749

DEC 10 2010

Submitter:

Quanta System SpA
via IV Novembre,116
21058 Solbiate
Olona VA / Italy

Contact:

Dr. Isabella Carrer
Medical Division Manager

Date Prepared: October 5, 2009

Device Trade Name: Quanta System Cyber Tm 150W

Common Name: Laser surgical instrument for use in general surgery and dermatology

Classification Name: Instrument, surgical, powered, laser

Predicate Devices:

- Quanta System **Cyber Surgical Laser Family (K090962)**;

Intended Use / Indications for Use:

2.01µm Applications:

The Cyber Tm 150W and its fiber optic delivery system are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including: Urology, Gastroenterology, Thoracic and Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery, General Surgery.and Arthroscopy

Urology

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Urethral Strictures
- Bladder Neck Incisions (BNI)

- Ablation and resection of Bladder Tumors, Uretheral Tumors and Ureteral
- Tumors.
- Ablation of Benign Prostatic Hypertrophy (BHP),
- Transurethral incision of the prostate (TUIP)
- Laser Resection of the Prostrate (HoLRP)
- Laser Enuculeation of the Prostate (HoLEP)
- Laser Ablation of the Prostate(HoLAP)
- Condylomas
- Lesions of external genitalia

Gastroenterology

Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Appendectomy
- Polyps
- Biopsy
- Gall Bladder calculi
- Biliary/Bile duct calculi
- Ulcers
- Gastric ulcers
- Duodenal ulcers
- Non Bleeding Ulcers
- Pancreatitas
- Hemorrhoids
- Cholecystectomy
- Benign and Malignant Neoplasm
- Angiodysplasia
- Colorectal cancer
- Telangiectasias
- Telangiectasias of the Osler-Weber-Renu disease
- Vascular Malformation
- Gastritis
- Esophagitis
- Esophageal ulcers
- Varices
- Colitis
- Mallory-Weiss tear
- Gastric Erosions

Gynecology

Open and laparoscopic gynecological surgery (incision, excision, resection,
ablation, vaporization, coagulation and hemostasis)

- Intra-uterine treatment of submucous fibroids, benign endometrial polyps,
- and uterine septum by incision, excision, ablation and or vessel
- coagulation
- Soft tissue excision procedures such as excisional conization of the cervix

ENT

Endoscopic endonasal surgery (incision, excision, resection, ablation,
vaporization, coagulation and hemostasis of soft tissue) including:

- Endonasal/sinus Surgery
- Partial turbinectomy
- Polypectomy
- Dacryocystorhinostomy
- Frontal Sinusotomy
- Ethmoidectomy
- Maxillary antrostomy
- Functional endoscopic sinus surgery
- Lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal
- Tonsillectomy
- Adenoidectomy

General Surgery

Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Cholecystectomy
- Lysis of adhesion
- Appendectomy
- Biopsy
- Skin incision
- Tissue dissection

- Excision of external tumors and lesions
- Complete or partial resection of internal organs, tumors and lesions
- Mastectomy
- Hepatectomy
- Pancreatectomy
- Splenectomy
- Thyroidectomy
- Parathyroidectomy
- Herniorrhaphy
- Tonsillectomy
- Lymphadenectomy
- Partial Nephrectomy
- Pilonidal Cystectomy
- Resection of lipoma
- Debridement of Decubitus Ulcer
- Hemorrhoids
- Debridement of Statis Ulcer
- Biopsy

Arthroscopy

Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and
cartilaginous tissue)

- Ablation of soft and cartilaginous tissue in Minimal Invasive Spinal
- Surgery including
- Percutaneous Laser Disc Decompression/Discectomy
- Foraminoplasty
- Ablation and coagulation of soft vascular and non vascular tissue in
- minimally invasive spinal surgery.

The Cyber Tm 150W is a surgical laser instrument for use in general surgery and dermatology.
The Cyber Tm 150W is:

Technological Characteristics:

Models	Wavelength	Laser Power
Cyber Tm	2.01μm	150W

- **Cyber Tm** is intended for use in surgical procedures using open, laparoscopic and

endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including: Urology, Gastroenterology, Thoracic and Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery, General Surgery and Arthroscopy

The device consists of a rack that houses the cooling units (2 chillers), the laser source and the power supply. Above the rack, into a cover-proof light, the laser head and optical bench with the beam delivery optics and the power meter are housed.
The Cyber Tm includes a Tm:YAG Laser Source that emit a Cw laser light at 2.01µm wavelength with power adjustable from 5 to 150W.
An SMA connector allows the connection of an optical fiber in which the main beam and the 650nm aiming beam are launched. Sidefire fibers (600µm) and bare fibers (200, 365, 400, 550, 600, 800 and 1000µm) are available for both laser source.
The emergency red push button , the key-switch and the operation status led are housed in the front part of the system.
The footswitch connector is housed in the back side of the system. A metal door closes the lower rack.
On the back panel are housed the magneto-thermal switch (circuit braker), the line cable with IEC309 /32A plug and a safety interlock connector. The rear panel also contains the power supply and chiller outlet grids cooling .
The device is controlled by a touch-screen PC mounted on a orientable arm.

Performance Data

Animal tests were performed to demonstrate the consistent and predictable ablation and coagulation of different tissues used in the study.

Substantial Equivalence:

Quanta System Cyber Tm 150W is as safe and effective as the predicate devices. The Cyber Tm 150W has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Cyber Tm 150W and its predicate devices raise no new issues of safety or effectiveness. From a clinical point of view, comparing 120W vs 150W application on animal tissue it has been showed that:

- lateral coagulation width and axial coagulation depth do not show any

significant difference – therefore the remaining tissue is affected in the same amount

- depth of the ablation crater: no significant differences when velocities of 5 and 10mm/s were used, while a significant increase of ablation depth at 1mm/s at 150W compared to 120W
- carbonisation of Tm:YAG laser power occurred at 150W in the same manner as could be observed at 120W

Thus, the Cyber Tm 150W is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Quanta System SPA
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street, NW
Buffalo, Minnesota 55313

DEC 10 2010

Re: K102749
Trade/Device Name: Quanta System Cyber Tm 150W
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: November 27, 2010
Received: December 01, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K102749

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- Ulcers
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- Angiodysplasia
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Prescription Use __X___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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and Restorative Devices

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